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EXAMINER	
CHANG, ROSIE YUH LOO	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,853	PACETTI ET AL.	
	Examiner	Art Unit	
	ROSIE YL CHANG	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-23, 25-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's cancellation of claims 1-6 and 24, and the addition new claims 25-80, in the paper filed in 9/12/2003 is acknowledge.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 recites the limitation " the pores". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 27-29 and 34 are rejected under U.S.C. 102 (e) as being anticipated by Taylor et al. (US 6,214,115).

Taylor et al. ('115) teach a process of coating a stent (col. 1, line 23-24). The stent of Taylor et al. ('115) is positioned on a support member (col. 1, line 27-28) i.e. a member of the mounting assembly, which is a rigid hollow conduit with apertures formed therein (col.1, line 42-45) i.e. porous surface. The stent mounted on the support member is dipped to coating liquid reservoir to form a coating layer on stent (col. 2, line 57-58). Taylor et al. ('115) further teach said support member have two collars arranged to engage with each end of the stent (col. 1, line 52-53).

As for claims 28:

The pores on the surface of the support member in the teaching of Taylor et al. ('115) are interconnected through the hollow conduit of the support member so as to provide an open pore system on said support member (see Fig. 2).

As for claim 27:

Taylor et al. ('115) further teach a sheath is placed around the external periphery of the support member and the sheath has one or more spiral slots formed around its outer surface (col. 3, Line 23-26), thus providing a closed pore system on the porous surface.

As for claims 29 and 34:

Taylor et al. ('115) further teach that (col. 3, line 21-23 and also see Fig. 3) a sheath formed from a plastic material, i.e. polymer, ceramic or other appropriate material is placed around the external periphery of the support member. The sheath made with polymeric material has a plurality of apertures, i.e. pores. A sheath of polymer material with pores on the surface would inherently form an absorbing layer on support member also inevitable absorbing some of the coating composition during the application of the coating process.

The said support member of the teaching of Taylor et al. ('115) is disclosed in the above includes an absorbent material meet the limitation of current claim 34.

Claims 53, 55-58 are rejected under U.S.C. 102 (e) as being anticipated by Moein (US 6,572,644).

As for claim 53:

Moein ('644) teaches a process of coating stent (col. 2, line 14) by positioning a first end of the stent so that first end is supported by a first member of a mounting assembly; positioning second end of the stent so that second end is supported by a second member of said mounting assembly (col. 2, line 24-32); and applying a coating composition to said stent, wherein said first and second member (col. 3, line 50-55) consisting of grooves of any suitable shape, i.e. cavities, to facilitate reception and containment of the excess coating composition applied to stent during the coating process (col.3, line 46-51 and see Fig. 5).

As for claims 55 and 58:

Moein ('644) teaches a coating method, which comprise spraying (col.4, line 2) a coating composition including solvent and polymer dissolved in the solvent onto the stent (col. 5, line 7-9).

As for claims 56 and 57:

Moein ('644) further teaches that said mounting assembly is connected to a motor providing said stent rotating and moving directions along longitudinal axis of the stent (col.2, line 55-63).

Claims 17-18, 20-23, 25-26, 39, 47-52 are rejected under 35 U.S.C. 102 (e) as being anticipated by Heller et al. (2003/0,215,564).

Heller et al. ('564) teach several methods for coating stent (Abstract). In one embodiment, Heller et al. ('564) teach using a catheter as the mandrel or work support when coat the stent (page 6, [0086]). The mounting assembly of Heller et al. ('564) comprises a hollow tubular catheter having a central lumen and an inflatable balloon (page 2, [0025]) tip, i.e. first member and second member of the mounting assembly. The sent is mounted on the balloon tip (see fig. 7), i.e. the first end of stent is in contact with first member and second end of the stent is in contact with second member. Heller et al. ('564) do not specifically teach the porous surface of the catheter balloon tip. However, Heller et al. (page 4, [0048]) teach the catheter is a substantially tubular and generally flexible device that carried fluids into or out of the body. The porous surface of

the balloon is well established in the art of using with a stent for enabling the flow of fluids with respect to the stent. Therefore, one of ordinary skill in the art would have recognized the catheter balloon inherently has porous surface that capable receiving excess coating solution during the coating process, which meet claims 17-18 and 39.

As for claims 25-26 and 47-48:

Heller et al. ('564) teach that both end of stent are affixed to the rotatable spool via a wire which is threaded through the length of the catheter's central lumen, i.e. the third member of the mounting assembly, and emerges from a hole in the catheter's two ends, thus the said wire, i.e. the third member, is not in contact with the stent.

As for claims 20-23, 49-52:

The stent of the teaching of Heller et al. ('564) is rotating about a longitude axis of the stent (page 6, [0086]) and moving about a longitude axis of the stent (see Fig.2). The coating solutions of the teaching of Heller et al. ('564) consist of polymer and solvent (page 5, [0073] and [0074]). The coating solution is applied onto the stent by spraying (page 6, [0081])

Claims 64-66, and 70-72 are rejected under U.S.C. 102 (e) as being anticipated by Parsons et al (US 6,521,284).

As for claims 64-65:

Parsons et al. ('284) teach a coating stent (col. 9, line 12) process, wherein the stent is positioned on a mounting assembly consisting of a porous mandrel (col. 13, line 30) and two spacers i.e. two support members, connecting thereto. The said stent is supported by two spacers (col. 5, line 21-25), which provide support to the two ends of the stent and prevent the inner surface of said stent in contact said mandrel. Parsons et al. ('284) further teach a coating composition including a solvent and a polymeric material (col. 6, line 27-29) is deposited on the outer surface of said stent that is mounted on the mounting assembly (see fig. 2) disclosed in the above.

As for claims 70-72:

Parsons et al. ('284) teach that which is disclosed in the above. Parsons et al. ('284) further teach the porous mandrel can be made of any suitable material, such as sintered metal, ceramic and polymeric materials (col. 5, line 12-14). Porous polymeric material inherently would be able to absorb some of the coating material as required in claim 70. Parsons et al. ('284) teach the porous mandrel is not in contact with the inner surface with stent (col. 5, line 21-25) as disclosed above. The coating solution includes polymer and solvent (col. 6, line 27-29).

Claims 76-80 are rejected under 35 U.S.C. 102 (e) as being anticipated by Heller et al. (2003/0,215,564).

Heller et al. ('564) teach several methods of coating stent. In the other embodiment, Heller et al. ('564) teach the sent is mounted on a sleeve, which is mounted on a

mandrel (page 6, [0077]), i.e. a first member, a second member and a third member of the mounting assembly and the first member to support a first end of the stent, the second end to support a second end of the stent, and the third member extending through the stent and connecting the first member to the second member. Heller et al. ('564) further teach the sleeve (the support members) is made of any suitable material that functionally engages the surrounding stent to limit the amount of coating solution on the surface of the stent in contact (page 6, [0078]). The suitable materials for making the sleeve include silicone rubber, natural rubber and the like (page 6, [0077]). Therefore, one of ordinary skill in the art would have recognized the silicone rubber or natural rubber inherently capable to absorb some of the excess coating solution and the support sleeve in the invention of Heller et al. ('564) is made of an absorbent material.

As for claims 77-80:

Please see the rejection made for claims 23-26 and claims 49-52 in the above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 20-23, 30-33 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al ('115) in view of Castro et al (US 6,395,326).

Taylor et al ('115) teach which is disclosed in the above. Taylor et al ('115) fails to teach the stent is rotating and moving in the direction of along the axis of stent as a coating solution spraying thereon.

Castro ('326) teaches a process of coating stent (col. 2, line 64-66) by applying defined amounts of coating solution to the stent surface so as to reduce the excess of polymeric materials build-up thereon (col. 2, line 56-58). The stent of Castro ('326) is supported (col.3, line 6) on a holder assembly, i.e. a support member, during the coating deposition process (page 8, line 27-28). The holder assembly is coupled to a motion control system (col. 7, line 39-40) which has the capability of maneuvering said stent and said holder assembly along a predetermined path in the x, y, z directions (col. 4, line 60-63) and/or rotational directions (see Fig. 2B). The coating composition of Castro ('326) includes a solvent and a polymer (col. 3, line 3-4). The coating solution is deposited by nozzles (col. 4, line 45-46). Examiner takes official notice that one of ordinary skill in the art would recognize the interchangeability of spraying and depositing solution by nozzle as methods of applying a solution onto a stent.

Castro ('326) fails to teach the porous surface or the absorbing layer of the support member required for receiving the excess of coating solution.

Since Taylor et al. ('115) teach the coating method discussed above and Castro ('326) would have reasonably suggested coating a polymeric solution onto the stent which is positioned on a support member that also control the rotating and moving directions of

the stent. Therefore, it would have been obvious to one of ordinary skill in the art to use the teaching of Taylor et al. ('115) in the coating method of Castro ('326) to manage the process designed for reduce defects and cost of coating stent.

As for claim 19:

Castro ('326) teaches that which is disclosed in the above. The suitable stent to use in the teaching of Castro ('326) includes self-expandable and balloon expandable stents. However, neither Castro ('326) nor Taylor et al. ('115) specifically teach that use a partially expanding stent prior to applying the coating composition. Since Castro ('326) do not particular point out using the stent in the contracting or partially expanding state, therefore it would have been obvious to one of ordinary skill in the art to appreciate that stent in the teaching of Castro ('326) could be in either constricted or partially expanding state prior to applying the coating composition.

Claims 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. ('564) in view of Murayamaet et al. (US 5,229,211).

Heller et al. ('564) teach that which is disclosed in the above. Heller et al. ('564) teach the first or second member of the mounting assembly is a catheter with balloon tip and have a porous surface wherein, however Heller et al. ('546) fail to disclose the specific material that the catheter made thereof. However, because medical device such as catheters are well established in the art for devices insertion into a body can be made of materials such as stainless steel, polypropylene or ceramic material as

evidenced by Murayamaet et al. ('211) (col. 6, line 1-14). Therefore, it would have been obvious to one of ordinary skill in the art to have produced the first or second member of the mounting assembly in the teaching of Heller et al. ('564) from a material such as stainless steel, polypropylene or ceramic material.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. ('564) in view of Ding et al. (US 6,346,856).

Heller et al. ('564) teach that which is disclosed in the above. Heller et al. ('564) fail to teach the inwardly tapered ends of first and second member that penetrate at least partially in the first and second ends of the stent. However, because the inwardly tapered ends shape of catheter balloon are well established in the art as evidenced by Ding et al. ('856) (see Fig. 1a and Fig 1b). It is the Examiner's position; the size of the stent fixed on the balloon tip would have been obvious to vary within the coating process, if a shorter stent used in the teaching of Heller et al. ('564), then it would have both tapered ends of the balloon penetrate in the lumen of stent.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moein ('644). Moein ('644) teaches that which is disclosed in the above. Moein ('644) teaches the mounting assembly includes a third member, i.e. the mandrel, extending within the stent and securing the first member to the second member, i.e. the sets of spines that support the stent (col. 3, line 35-44). Moein ('644) further teaches that the distance between the sets of the spine (col. 3, line 37-41) depend on the design of the stent to be supported.

It is the Examiner's position, that the distance between first member and second member of the mounting assembly may be adjusted, since this would be a production process parameter which would not carry patentable weight.

Claims 67- 69, 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. ('284) in view of Moein ('644).

Parsons et al. ('284) teach that which is disclosed above. Parsons et al. ('284) fails to specifically teach the coating process is by spraying coating solution onto the stent and stent is rotating and moving about the axis of the stent. Moein ('644) teaches a stent mounting assembly that control the rotating moving directions of the stent. Moein ('644) teaches the coating composition is sprayed onto the stent. Since Parsons et al. ('284) teach part of the supporting member of the mandrel has the capacity to absorb the excess coating solution, therefore it would have been obvious to one of ordinary skill in the art to use the teaching of Parsons et al. ('284) in the invention of Moein ('644) to coat stent in a flexible way while also minimizing the defect in producing coated stent.

Claims 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. ('564) in view of Ding et al. (US 6,364,856).

Heller et al. ('564) teach that which is disclosed in the above. Heller et al. ('564) fail to teach either first or second member of the mounting assembly includes a layer of absorbance material disposed thereon.

Ding et al. ('856) teach a method to depose a polymeric sponge layer on the surface of the catheter balloon (col. 2, line 59-62). The sponge layer has a plurality of voids (col. 2, line 66) inherently capable of absorbing excess coating solution. Since Heller et al. ('564) teach the stent is mounted on catheter with balloon tip, and the stent is supported by the catheter and its balloon tip during the coating process; and Ding et al. ('856) teach a sponge layer applied on the surface of the catheter balloon would facilitate transferring drug and fluids in and out of the catheter balloon. Therefore, it would have been obvious to one of ordinary skill in the art to use the teaching of Ding et al. ('856) in the coating method of Heller et al. ('564) to remove excess coating solution and minimize the build-up on the stent surface.

As for Claims 60-64:

As disclosed in the above, Heller et al ('856) teach the stent is rotating about a longitude axis of the stent (page 6, [0086]) and moving about a longitude axis of the stent (see fig. 2). The coating solutions of the teaching of Heller et al. ('564) consist of polymer and solvent (page 5, [0073] and [0074]) and which is sprayed onto the stent (page 6, [0081]).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSIE YL CHANG whose telephone number is 571-272-6466. The examiner can normally be reached on MONDAY TO FRIDAY 7: 00AM TO 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIMOTHY MEEKS can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEITH HENDRICKS
PRIMARY EXAMINER